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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,393	11/17/2003	Quan Nguyen	70-000410US	4409

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	**PAPER NUMBER**
1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/716,393	NGUYEN ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *103-151 and 202-204* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *103-151 and 202-204* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 103, 105-113, 116-129, 131-142, drawn to a composition comprising a caged RNA wherein the caged RNA comprises at least one double-stranded region, and to a kit comprising the caged RNA, classified in class 536, subclass 24.5. **Upon election of this group, applicant is required to elect a single species of cellular delivery modules and of label and quencher locations, as explained below.**

II. Claims 104-107, 115-117, 120, 121, 130-136, and 138-142, drawn to a composition comprising a caged RNA wherein the caged RNA comprises a single polyribonucleotide strand comprising an antisense strand, and to a kit comprising the caged RNA, classified in class 536, subclass 24.5. **Upon election of this group, applicant is required to elect a single species of cellular delivery modules, as explained below.**

III. Claims 143-151, drawn to a method of selectively attenuating expression of a target gene in a cell comprising introducing a caged RNA into the cell, wherein the caged RNA comprises at least one double stranded region, classified in class 514, subclass 44.

IV. Claims 143-151, drawn to a method of selectively attenuating expression of a target gene in a cell comprising introducing a caged RNA into the cell,

wherein the caged RNA comprises a single polyribonucleotide strand comprising an antisense strand, classified in class 514, subclass 44.

V. Claims 202-204, drawn to a method of selectively attenuating expression of a target gene in a cell comprising introducing a first caged DNA and a second caged DNA into the cell, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions of groups I and II are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. The inventions of groups I and II are directed to separate and distinct compounds. A search for the RNA comprising at least one double stranded region would not necessarily return art against the RNA comprising a single polyribonucleotide strand. Therefore, to search more than one of the above inventions in the same application presents an undue search and examination burden.

Inventions of groups I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of selectively attenuating expression of a target gene in a cell can be practiced with a single stranded oligonucleotide, which does not involve the double stranded molecule of group I. A search for the composition of group I would not necessarily return art against the method of group III. Therefore, to search more than one of the above inventions in the same application presents an undue search and examination burden.

Inventions of groups I and IV are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the caged RNA comprising at least one double-stranded region is not an element of the method of using a caged RNA comprising a single polyribonucleotide strand comprising an antisense strand. A search for a method of selectively attenuating expression of a target gene in a cell comprising introducing a caged RNA comprising a single polyribonucleotide strand comprising an antisense strand would not necessarily return art against a caged RNA comprising at least one double-stranded region. Therefore, to search more than one of the above inventions in the same application presents an undue search and examination burden.

Inventions of groups I and V are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant

case, the caged RNA comprising at least one double-stranded region is not an element of the method of group V. A search for a method of selectively attenuating expression of a target gene in a cell comprising introducing a first caged DNA and a second caged DNA into the cell would not necessarily return art against a caged RNA comprising at least one double-stranded region. Therefore, to search more than one of the above inventions in the same application presents an undue search and examination burden.

Inventions of groups II and III are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the caged RNA comprising a single polyribonucleotide strand comprising an antisense strand is not an element of the method of using a caged RNA comprising at least one double stranded region. A search for a method of selectively attenuating expression of a target gene in a cell comprising introducing a caged RNA comprising at least one double stranded region would not necessarily return art against a caged RNA comprising a single polyribonucleotide strand. Therefore, to search more than one of the above inventions in the same application presents an undue search and examination burden.

Inventions of groups II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method

of selectively attenuating expression of a target gene in a cell can be practiced with a double stranded RNA molecule, which does not involve the single stranded polyribonucleotide of group II. A search for the composition of group II would not necessarily return art against the method of group IV. Therefore, to search more than one of the above inventions in the same application presents an undue search and examination burden.

Inventions of groups II and V are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the caged RNA comprising a single polyribonucleotide strand comprising an antisense strand is not an element of the method of group V. A search for a method of selectively attenuating expression of a target gene in a cell comprising introducing a first caged DNA and a second caged DNA into the cell would not necessarily return art against a caged RNA comprising a single polyribonucleotide strand comprising an antisense strand. Therefore, to search more than one of the above inventions in the same application presents an undue search and examination burden.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is

subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to the following patentably distinct species in claims 132 and 135: a polypeptide, a PEP-1 peptide, an amphipathic peptide, an MPGNLS peptide, a cationic peptide, a homopolymer of D-arginine, a homopolymer of histidine, a homopolymer of lysine, a protein transduction domain, a protein transduction domain derived from an HIV-1 Tat protein, from a herpes simplex virus VP22 protein, or from a Drosophila antennapedia protein, a model protein transduction domain, or a model protein transduction domain comprising a homopolymer of D-arginine, a lipid, or one or more myristoyl groups.

Each of the above listed species of compounds are separate and distinct, containing no common structural core.

Furthermore, this application contains claims directed to a multitude of patentably distinct species in claims 125, 126, 128, and 129. Each of the configurations of label and quencher locations is considered separate and distinct, each requiring a separate and distinct search based on the specific structure of the molecules.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

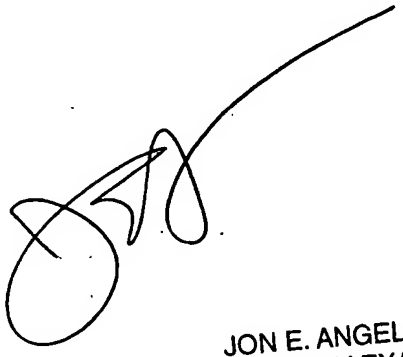
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy H Bowman
Examiner
Art Unit 1635

AHB



JON E. ANGELL, PH.D.
PRIMARY EXAMINER